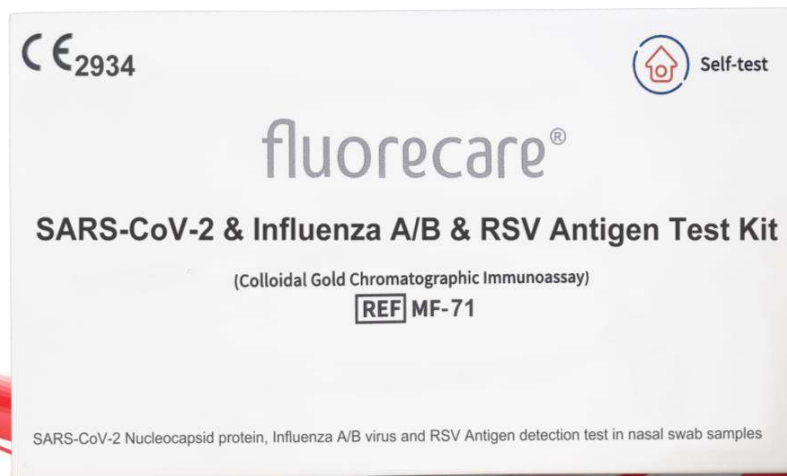


# fluorecare<sup>®</sup>

CE<sub>2934</sub>



## **SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (self-testing)**

**MF-71**

**Product Brochure**



**Microprofit  
Biotech**



**SARS-CoV-2**

**Influenza A/B**

**RSV**

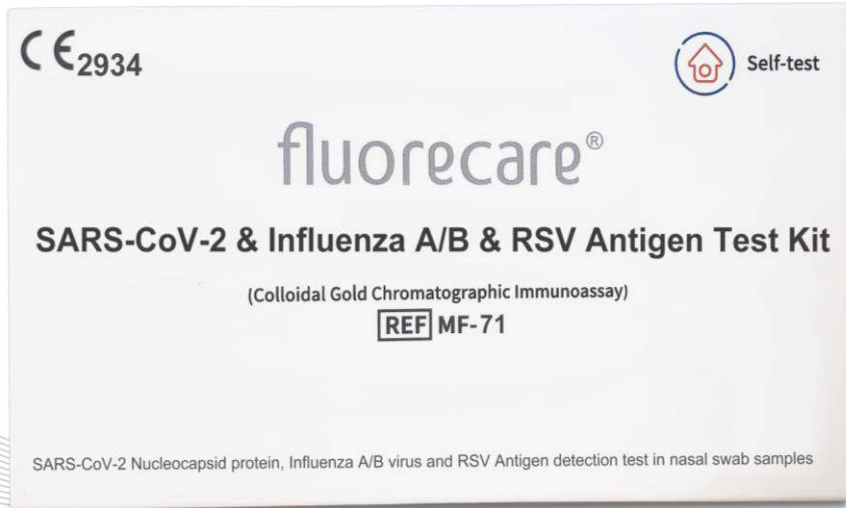
**Combo Test Kit**

## Advantages

1. Rapid : Results in 15 mins
2. Non-invasive diagnosis : Nasal swab sample
3. Efficiency : Rapidly differentiate 4 infections in 1 test
4. Convenient : Easy operation and no need for extra Equipment
5. Storage: No need refrigerated transportation and store at room temperature
6. It is effective for Alpha, Beta, Gamma, Delta and Omicron

## Characteristics

<b>Method</b>	Colloidal Gold
<b>Test Time</b>	15 min
<b>Shelf Life</b>	18 months
<b>Sample Type</b>	Nasal swab
<b>Specification</b>	Kits for 1T, 2T, 5T
<b>Storage</b>	Room temperature (2-30°C)



## Test Kit



**Test card Tube Test card bag Swab Introduction**

## CERTIFICATE

DIRECTIVE 98/79/EC  
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

**Shenzhen Microprofit Biotech Co., Ltd.**

Rm. 405, 406, Zone B/4F, Rm. 205, 206-1, 207, West Side  
of Zone B/ 2F, Haowei Building, No. 8 Langshan 2nd  
Road, Songpingshan, Songpingshan Community,  
Xili Street, Nanshan District, Shenzhen, P.R. China

*in vitro* diagnostic medical device for self-testing

**fluorecare SARS-CoV-2 & Influenza A/B  
& RSV Antigen Combo Test Kit**  
catalogue numbers: MF-71-1, MF-71-2, MF-71-5

in term of the design conforms to the requirements of Annex III  
section 6 to Directive 98/79/EC (as amended) implemented into Polish  
Law, as evidenced by the assessment conducted  
by CeCert Sp. z o.o.

**CE** **2934**

Validity date: 12.05.2022 – 26.05.2025

Edition issue date: 18.05.2022

Check it



CeCert Sp. z o.o.  
ul. Żurawia 32/34  
00-515 Warszawa

Kamil Szczurowski  
Director of *in Vitro* Diagnostic Medical Device  
Certification Department

# Clinical Accuracy

## 1. Results and Analysis of SARS-CoV-2

Method		RT-PCR		Total Results
SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	342	0	342
	Negative	26	450	476
Total Results		368	450	818

Positive correct rate ( Clinical sensitivity )at Ct<38=92.93%  
(95%CI:89.82%~95.33%)

Negative correct rate (Clinical specificity) = 100%  
(95%CI:99.18% ~100%)

Method		RT-PCR		Total Results
by Lay person	Results	Positive	Negative	
	Positive	30	0	30
	Negative	2	87	89
Total Results		32	87	119

## 2. Results and Analysis of Influenza A:

Method		Reference product		Total Results
SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	104	0	104
	Negative	9	555	564
Total Results		113	555	668

Clinical sensitivity =92.04% (95%CI:85.42% ~96.29%)

Clinical specificity =100.00% (95%CI:99.34%~100.00%)

Method		Reference product Professional test		Total Results
self-test	Results	Positive	Negative	
	Positive	17	0	17
	Negative	0	102	102
Total Results		17	102	119

### 3. Results and Analysis of Influenza B:

Method		Reference product		Total Results
SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	80	0	80
	Negative	8	580	588
Total Results		88	58-	668

Clinical sensitivity =90.91% (95%CI:82.87% ~95.99%)

Clinical specificity =100.00% (95%CI:99.37%~100.00%)

Method		Reference product Professional test		Total Results
self-test	Results	Positive	Negative	
	Positive	11	0	11
	Negative	1	107	108
Total Results		12	107	119



## 4. Results and Analysis of RSV:

Method		Reference product		Total Results
	Results	Positive	Negative	
SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Positive	63	0	63
	Negative	3	602	605
Total Results		66	602	668

Clinical sensitivity =95.45% (95%CI:87.45% ~99.05%)

Clinical specificity =100.00% (95%CI:99.39%~100.00%)

Method		Reference product Professional test		Total Results
	Results	Positive	Negative	
self-test	Positive	31	0	31
	Negative	1	87	88
Total Results		32	87	119



# About us

Microprofit Biotech is a national high-tech enterprise from China, the headquarter – Microprofit Building located in the center of Shenzhen city. As an ISO13485 qualified manufacturer since 2009, microprofit biotech specialized in R&D Manufacture, and Marketing of In-Vitro Diagnostics (IVD) analyzers and test kits with the idea of POCT (point-of-care-testing). Our products were reliable, easy to use and easily accessible.



Our official brand fluorecare, is dedicated to entire products of point-of-care (POC) tests using immunofluorescence quantitative assay to monitor and prognosis of human diseases with comprehensive parameters, including tumor, hormone, cardiac, infection and diabetes markers.

Up to the year 2020, the laboratory diagnostic kits of microprofit biotech has been serving almost every top hospitals in China, and laboratories/hospitals/clinics in 40+ countries globally, including Germany, Belgium, Italy, Philippines, Indonesia, Ecuador, Peru, Nigeria, South Africa...



# Microprofit Biotech

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